Siemens Medical Solutions USA, Inc. Ultrasound Division

SEP 2 2 2005

ACUSON Sequoia™ Ultrasound System Special 510(k) Submission

#### **SECTION 11**

#### 510(k) Summary of Safety and Effectiveness

Sponsor:

Siemens Medical Solutions USA, Inc., Ultrasound Division

1230 Shorebird Way

P.O. Box 7393

Mountain View, California 94039-7393

Contact Person:

Iskra Mraković

Manager, Regulatory Affairs Telephone: (650) 694-5004

Fax: (650) 943-7053

Submission Date:

September 1, 2005

Device Name:

Sequoia Diagnostic Ultrasound System

Common Name:

Diagnostic Ultrasound System with Accessories

#### Classification:

Regulatory Class: II Review Category: Tier II

Classification Panel: Radiology

#### 21 CFR 892.1550

	<u>FR #</u>	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Diagnostic Intravascular Catheter	870.1200	90-DQO

#### Predicate Device:

 # K051139 (May 13, 2005) cleared as ACUSON Sequoia<sup>™</sup> Diagnostic Ultrasound System.

#### Device Description:

The Sequoia system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product that is already cleared for USA distribution under the following 510(k) PreMarket Notification number:

 # K051139 (May 13, 2005) cleared as ACUSON Sequoia<sup>™</sup> Diagnostic Ultrasound System.

The Sequoia Diagnostic Ultrasound System has been designed to conform to the following *product safety standards*:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-2, 1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Device Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- ISO 10993 Biocompatibility
- The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

#### Intended Use:

The Sequoia platform is intended for use in the following applications:

General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid, penis and prostate), Neonatal/Adult Cephalic, Cardiac (adult, pediatric, and neonatal), Trans-esophageal, Transrectal, Transvaginal, Peripheral Vessel, and Musculo-sceletal (superficial and conventional) applications, and intended uses as defined in the FDA guidance document.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

#### Technological Comparison to Predicate Device:

The Sequoia is substantially equivalent in its technologies and functionality to the Sequoia Diagnostic Ultrasound System that is already cleared under 510(k) premarket notification number K051139.

The Sequoia functions in the same manner as other diagnostic ultrasound systems, in that they transmit ultrasonic energy into the body *via* a transducer. In the body, acoustic impedance of different tissues reflect different amounts of ultrasound energy back to the transducer, where post processing of received echoes is performed to generate two-dimensional on-screen images of anatomic structures and fluid flow within the body. Doppler principles are used to process reflected ultrasound energy to display moving blood as a spectrum, or as color-coded two-dimensional images. All predicate devices listed above, allow for specialized measurements of structures and flow, and provide various calculations' functions.

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SEP 2 2 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Iskra Mraković Manager, Regulatory Affairs Siemens Medical Solutions USA, Inc. 1230 Shorebird Way P.O. Box 7393 MOUNTAIN VIEW CA 94039-7393

Re: K052410

Trade Name: Sequoia™ Ultrasound System

Regulation Number: 21 CFR 892.1550, 21 CFR 892.1560, and 21 CFR 892.1570

Regulation Name: Ultrasonic pulsed doppler imaging system

Ultrasound pulsed echo imaging system

Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: September 1, 2005 Received: September 2, 2005

#### Dear Mr. Mraković:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Sequoia™ Ultrasound System, as described in your premarket notification:

#### Transducer Model Number

<u>4C1</u>	<u>EV8C4</u>
<u>5C2</u>	<u>6L3</u>
6C2	<u>8L5</u>
8C4	<u>8L5T</u>
EC10c5	<u>13L5SP</u>

<u>15L8</u> 15L8w	7V3c 8V3
V5M TEE	<u>8V5</u>
<u>V7M TEE</u> V7B TEE	<u>10V4</u> AUX CW
<u>3V2c</u>	AcuNav (IC10V5 or 10F) Ultrasound
<u>4V1</u> 4V1c	<u>Catheter</u> AcuNav 8F Ultrasound Catheter
4V2	Apollo
5V2c	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known):

Device Name:

Sequoia™ Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						P	P	<del> </del>	P*	P
Fetal		P	P	P	P	P	P		p*	P
Abdominal		P	P	P	P		P		P*	P
Intraoperative Abdominal		P _	P	P	Р	P			p*	P
Intraoperative Neurological		P	P	P	P	P	P	ļ		
Pediatric	1	P	P	P	P	P	P		p*	P
Small Organ (specify)**	1	P	P	P	Р	Р	P		p*	P
Neonatal Cephalic	╅┈	P	P	P	P	P	P		P*	P
Adult Cephalic	+-	P	P	P	P	P	P		P*	P
Cardiac	+	P	P	P	P	P	P		P*	P
	<del>-  </del>	T P	P	P	P	P	P		P*	P
Trans-esophageal Transrectal	┥─	<del>  </del>	÷	P	P	P	P		P*	P
Transveginal		P	<del>  i</del>	P	P	P	P		P*	P
Transvaginal	-	+-	+ -	+ -	<del> </del>	1				
Intravascular		+-	<del> </del>	<del> </del>		<del> </del>				
Peripheral Vessel	$\dashv$	+ P	P	P	P	P	P		P*	P
Laparoscopic	+-	+-	+	<del> </del>	1	$\top$				
Musculo-skeletal (Conventional)	<u> </u>	P	P	Р	P	P	P		P*	P
Musculo-skeletal (Superficial)	<del></del>	P	P	P	P	P	Р		P*	P
Other (specify)***	+	P	<del> </del>	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, #K992631, #K992580, #K973767, #K935595/S1.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
**small organs (breast, testes, thyroid, penis)
***neonatal cardiac

(PLESE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

4C1

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic								ļ. <u>.</u>		 
Fetal		P	P	Р	P	P	P		P*	P
Abdominal		P	P	P	P	P	Р			<del>  -                                   </del>
Intraoperative Abdominal						ļ	ļ		<u> </u>	<u> </u>
Intraoperative Neurological			ļ 						P*	P -
Pediatric	1	P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P-	-
Neonatal Cephalic		T	1	Ĭ						<del>- </del>
Adult Cephalic			TT.				<u> </u>		p*	P
Cardiac		P	P	P	P	P	P			<del> </del>
Trans-esophageal			Ţ <u> </u>		<u> </u>				ļ. <u> </u>	<del></del>
Transrectal					<u> </u>					
Transvaginal	╗			1						
Transurethral		1								
Intravascular		<u> </u>					<del> </del>		- p*	P
Peripheral Vessel		P	P	P	P	P	P	<del></del>	<del></del>	-
Laparoscopic							<b>_</b>	<del> </del>		<del> </del>
Musculo-skeletal (Conventional)										ļ <u>-</u>
Musculo-skeletal (Superficial)				<u> </u>					<u> </u>	
Other (specify)		$\neg \vdash$					#K051130 #K0			

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, and #K002807.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
**small organs (breast, testes, thyroid, penis)
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	
(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number	

510(k) Number (if known):

Device Name:

5C2

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						P	 	<del> </del>	P*	P
Fetal	Τ_	P	Р	P	P		P	<del> </del>	P*	P
Abdominal		P	P	P	P	P	<u> </u>	<del> </del>	<del>                                     </del>	-
Intraoperative Abdominal								<u> </u>		<del> </del>
Intraoperative Neurological			ļ							 
Pediatric		P	P	P	P	P	Р	<del> </del>	<del>                                     </del>	<del>+                                    </del>
Small Organ (specify)**						<u> </u>				ļ
Neonatal Cephalic						<u> </u>		<del>- </del>		<del> </del>
Adult Cephalic					<u> </u>	1	P	<del></del>	P*	P
Cardiac		P	P	P	P	P	P		<del></del>	<del>                                     </del>
Trans-esophageal		1_	<u> </u>				_			-
Transrectal							<del></del>	<del></del>	<del></del>	<del> </del>
Transvaginal			1_		ļ		<del> </del>		<del></del>	<del>                                     </del>
Transurethral			1_			<del> </del>	<del> </del>			<del>                                     </del>
Intravascular			_			- n			P*	P
Peripheral Vessel		P	P	P	P	P	<del>                                     </del>	<del></del>	1	
Laparoscopic							<del></del>			<del>                                     </del>
Musculo-skeletal (Conventional)							<u> </u>			<del> </del>
Musculo-skeletal (Superficial)										
0.1 - (:6.)	$\neg \vdash$			Ţ			#K051139, #K0		0114 #1/0225	

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
p. Durp. Cala- Dander B. CWD-Color Donoler, B+Power Doppier,
B+PWD+Color Doppler, B+CWD+Color Doppler, B+CWD+Power Doppler, B+Clarify VE  B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number

510(k) Number (if known):

Device Name:

6C2

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						P	P		P*	P
Fetal	<u> </u>	P	P	P	P	1	P	<del>                                       </del>	P*	Р
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P	<b></b>	p*	P
Intraoperative Neurological		P	P	P	P	P				P
Pediatric	1	P	P	P	P	P	PP		P* P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	r
Neonatal Cephalic			<u> </u>	<u> </u>			ļ <u> </u>	<del></del>		-
Adult Cephalic				ļ	<u> </u>	<del> </del>	<del> </del>	<del>-</del>	p*	P
Cardiac	_ _	₽	P	P	P	P	r	<del>-</del>	<del></del>	+
Trans-esophageal								_	<del></del>	
Transrectal				<u> </u>		<u> </u>	<del></del>		<del></del>	
Transvaginal					_	<u> </u>	<u> </u>	<del>_</del>		-
Transurethral		$oldsymbol{\perp}$	<u>∟</u>	<u> </u>	_		<u> </u>	<del> </del>		
Intravascular			1_	J	<del></del>	<del></del>	P	_	P*	P
Peripheral Vessel		P	P	P	P_	P			<del>-  -                                  </del>	<del></del>
Laparoscopic				↓		<del> </del>		<del> </del>	<del> </del>	
Musculo-skeletal (Conventional)								<u> </u>	ļ	
Musculo-skeletal (Superficial)								<u> </u>	<u> </u>	
Other (specify)						1	WAS1120 #KA		<u> </u>	

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, and #K002807.

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+Clarify VE
**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

510(k) Number (if known):

Device Name:

8C4

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic							P	<del> </del>	p*	P
Fctal		P	P	P	P	P		<del> </del>	P*	P
Abdominal		P	P	P	P	P	P	<del></del>	p*	P .
Intraoperative Abdominal		P	P	P	P	P	P			P
Intraoperative Neurological		P	P	Р	P	P	P		P*	
Pediatric		P	P	P	P	P	P	<b>_</b>	P*	P_
Small Organ (specify)**								<u> </u>		<u> </u>
Neonatal Cephalic		Т_					<u> </u>			<del>                                     </del>
Adult Cephalic			Ì	<u> </u>		<u> </u>		<del>-</del>	P*	P
Cardiac		P	P	P	P	P	P		-	<del>-                                    </del>
Trans-esophageal				<u> </u>	<u> </u>	<del> </del>				+
Transrectal			1_	<u> </u>		<u> </u>		<del></del>	<del></del>	+ -
Transvaginal			<u> </u>			<del></del>		<del>- </del> -	<del></del>	<del> </del>
Transurethral			<u> </u>					<u> </u>		
Intravascular			1_		<u> </u>		<del> </del>	<del> </del>	p*	- P
Peripheral Vessel		P	P	P	P	P	P		<del></del>	<del>                                     </del>
Laparoscopic			1_	1			_		<del></del>	<del></del>
Musculo-skeletal (Conventional)										<del> </del>
Musculo-skeletal (Superficial)					ļ			<u> </u>		ļ
Other (specify)					1				1	

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+Clarify VE

(PLESE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ...

510(k) Number (if known):

Device Name:

EC10c5

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic								<del> </del>	<del> </del>	<del> </del>
Fctal	1 _	<u> </u>	L		ļ	<del> </del>	<del> </del>		<del> </del>	<del> </del>
Abdominal		<u> </u>		<u> </u>	ļ	ļ	<del> </del>	<del> </del>		
Intraoperative Abdominal					<u> </u>			<u> </u>	<u> </u>	<u> </u>
Intraoperative Neurological		_						ļ		
Pediatric				<u> </u>		<del> </del>	<u> </u>		<del> </del>	
Small Organ (specify)**				<u> </u>						
Neonatal Cephalic		1_	T	<u> </u>			<del> </del>		<del> </del>	
Adult Cephalic		$\top$		1		ļ		<del> </del>		
Cardiac			<u> </u>	<u> </u>						<u> </u>
Trans-esophageal			<u> </u>			<del> </del>	- P	<del>-</del>	P*	P
Transrectal		P	P	P	P	P	P P			P
Transvaginal	J.,	P	P	P	P	P	- r	<del></del>	<del>                                   </del>	
Transurethral				<u> </u>			<del> </del>		<del></del>	
Intravascular				<u> </u>					<u>-</u>	<del></del>
Peripheral Vessel			↓		_	<del></del> -			<del></del>	
Laparoscopic			1_				<del> </del>			
Musculo-skeletal (Conventional)			<u> </u>	<u> </u>						
Musculo-skeletal (Superficial)										
Other (specify)	1	$\top$			- [		#K051139, #K04			

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, and #K002807.

**Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

(PLESE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number \_

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

EV8C4

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthaimic	<u> </u>					P	P	<u> </u>	p*	P
Fetal	1	P	P	P	P		P	<del></del>	p*	P
Abdominal	<u> </u>	P	P	P	P	P	- P	<del> </del>	<del> </del>	1
Intraoperative Abdominal							<u> </u>	<u> </u>	<del> </del>	
Intraoperative Neurological			<u> </u>		<u> </u>		<u> </u>	<u> </u>		<del> </del>
Pediatric		$\mathbb{T}$			<u> </u>	ļ	ļ	<u> </u>	<del>                                     </del>	+
Small Organ (specify)**				<u> </u>						
Neonatal Cephalic										<del></del>
Adult Cephalic		<u> </u>	1	<u> </u>	<u> </u>			<del> </del>	<del> </del>	<del> </del>
Cardiac		T	١_				_\	_	<del></del>	
Trans-esophageal		<u> </u>		1				<del>                                     </del>		<del></del>
Transrectal			1			<del> </del>	P	<del></del>	P*	P
Transvaginal		P	P	P	P	P	<u> </u>		<u> </u>	<del> </del> -
Transurethral				<u> </u>			<del> </del>	<del></del>	<del>                                     </del>	
Intravascular			1_				<u> </u>	<del>_</del>		<del> </del>
Peripheral Vessel			<u> </u>	<u> </u>			<u> </u>	<del> </del>		
Laparoscopic			<u> </u>			<del> </del>			<del> </del>	
Musculo-skeletał (Conventional)			ļ 		ļ					
Musculo-skeletal (Superficial)								 	ļ	
Other (specify)		$\top$	$\top$				 #K051139_#K04		<u> </u>	

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
R+PWD+Color Doppler B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

6L3

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						P	P	<del></del>	P*	P
Fetal	1	P	P	P	P	<u> </u>	<del> </del>		<del> </del>	<del> </del>
Abdominal	<u> </u>	1_		<u> </u>	<del> </del>	P	P -	<del>                                     </del>	P*	P
Intraoperative Abdominal		P	P	P	P	<u> </u>		<u> </u>	p*	 
Intraoperative Neurological		P	P	P	P	P	P	ļ <u>-</u>		<u> </u>
Pediatric				P*	P					
Small Organ (specify)**		P	P	P	P	P	P			
Neonatal Cephalic							<u> </u>			
Adult Cephalic			]	<u> </u>			1	<del> </del>	P*	P
Cardiac		P	P	P	P	P	P		<u> </u>	<del> -                                    </del>
Trans-esophageal							<u> </u>		<b></b>	<del> </del>
Transrectal							<u> </u>			
Transvaginal			1	<u></u>			<u> </u>		<del> </del>	
Transurethral							<u> </u>			+
Intravascular			1	<u> </u>			<u> </u>		p*	P
Peripheral Vessel		P	P	P	P	P	P			<del></del> *-
Laparoscopic				<u> </u>				_}		P
Musculo-skeletal (Conventional)		P	P	P	P	P	P			
Musculo-skeletal (Superficial)		P	P	P	P	P	P	_	P*	P
Other (specify)			7				#K051139. #K0	l		

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:	
Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,	
L+PWD+Color Doppler B+CWD+Color Doppler, B+Power Doppler,	
8+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE	
*small organs (breast, testes, thyroid, penis)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number \_\_\_\_\_

510(k) Number (if known):

Device Name:

8L5

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic							ļ	<del> </del>		<del> </del>
Fetal						ļ	<del> </del>	<del>-                                    </del>	<del> </del>	<del>                                     </del>
Abdominal		1_		<b> </b>	<u> </u>	P	P		p*	P
Intraoperative Abdominal		P	P	P	P		P		p*	P
Intraoperative Neurological		P	P	P	P	P	ļ <sup>P</sup>	<u> </u>		
Pediatric		D D P P P	P*	P						
Small Organ (specify)**		P	P	P	P	P	F			
Neonatal Cephalic										<del></del>
Adult Cephalic		Ţ	<u>l                                    </u>	<u> </u>		<u> </u>	P		P*	P P
Cardiac	T	P	P	P	P	P		<del> </del>		<del> </del>
Trans-esophageal		]_	_	<u> </u>			<del> </del>	<b></b>		+
Transrectal			<u> </u>	ļ					<u> </u>	<del> </del>
Transvaginal		_	1			<u> </u>				
Transurethral			↓_	<u> </u>			<del> </del>		.	
Intravascular			<u> </u>				P		p*	P
Peripheral Vessel		P	P	P	P	P			<del>  -                                   </del>	<del>                                     </del>
Laparoscopic				<del></del>		<del> </del>	P	<del></del>	p*	P
Musculo-skeletal (Conventional)		P	P	P	P	P			p*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	Р			ļ <u>'</u>
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:	B+CWD, B+Color Doppler, B+M+ Color Doppler,
R+PWD+Color Doppler, B+CWD+Colo	r Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power I	Doppler, B+CWD+Power Doppler, B+Clarify VE
**small organs (breast, testes, thyroid, pa	enis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

8L5T

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic					Ţ			<del> </del>		<del> </del> -
Fetal	J	1		ļ	<u> </u>	ļ			<del></del>	
Abdominal					<u> </u>	<del> </del>	P			P
Intraoperative Abdominal		P	P	P	P	P			p*	P
Intraoperative Neurological		P	P	P	P	P	P			P
Pediatric	+	P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	ļ
Neonatal Cephalic			<u> </u>	<u> </u>	<u> </u>	<u> </u>				
Adult Cephalic				<u> </u>		_ <del> </del>	<del></del>			P
Cardiac		P	P	P	P	P	Р			+
Trans-esophageal				<u> </u>	1			- <b> </b>	<del></del>	-
Transrectal			1_							
Transvaginal		<u> </u>	<u> </u>		<u>.                                    </u>		_[			<del></del>
Transurethral				<u> </u>	_		<del> </del>		<del>- </del>	+
Intravascular			<u> </u>				P	<del></del>	p*	P
Peripheral Vessel		P	P	P	P	P	r	<del> </del>	<del> </del>	<del></del>
Laparoscopic			<u> </u>				P	<del> </del>	P*	
Musculo-skeletal (Conventional)		P	P	P	P	P			p*	- P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	
Other (specify)		$\top$		-			#K051139_#K04			

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, and #K022567.

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,  B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,  B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

13L5SP

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						ļ	<u> </u>	<del> </del>	<del> </del>	<del> </del>
Fetal		<u>                                      </u>		ļ	<del> </del>	ļ. —		<del> </del>	<u> </u>	
Abdominal		<u> </u>			<del> </del>	_ P	Р -	+	P*	P
Intraoperative Abdominal		P	P	P	P	<u> </u>	l		p*	P
Intraoperative Neurological		P	P	P	P	P	P			
Pediatric	+-	P	P	P	P	P	P		P*	P
Small Organ (specify)**	1-	P	P	P	P	P	P		P*	P
Neonatal Cephalic		Ţ	T		<u> </u>		<u> </u>			<del> </del>
Adult Cephalic		1	1	1			ļ	+	p*	P
Cardiac		P	P	P	P	P	P	<b>_</b>		<del>-  </del>
Trans-esophageal	1	T	Ţ <u></u>	Ţ		<u> </u>			<del></del>	<del></del>
Transrectal		Ţ			J					<del></del>
Transvaginal		1_	1	<u> </u>					<u> </u>	
Transurethral			1						<del> </del>	
Intravascular	$\top$		1	<u> </u>					p*	P
Peripheral Vessel		P	P	P	P	P	PP			<del>-  -                                  </del>
Laparoscopic			1	<u> </u>					p*	P
Musculo-skeletal (Conventional)		P	P	P	P	P	P	<u> </u>		
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, and #K022567.

Additional Comments:  Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+Clarify VE B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
*small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

15L8

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic							<u> </u>		<del> </del>	<del></del>
Fetal		l _	<u> </u>			<u> </u>	<u> </u>		<del></del>	
Abdominal						<u> </u>	ļ <del></del>	<b></b>	P*	P P
Intraoperative Abdominal		P	P	P	P	P	P		p*	, P
Intraoperative Neurological		P	P	P	P	P	P		ļ	
Pediatric	+	P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic			}		1	<u> </u>				<del> </del>
Adult Cephalic		1	1	T					- 5+	P
Cardiac	7	P	P	P	P	P	P		P*	r
Trans-esophageal		1	1_				<u> </u>			<del> </del>
Transrectal	7	1						_		
Transvaginal				ļ						_
Transurethral				L. <u>_</u>		<u> </u>	<u> </u>		<u> </u>	<del>                                     </del>
Intravascular				1					D*	P
Peripheral Vessel		P	P	P	P	P	P		- P-	- r
Laparoscopic						<u> </u>			p*	P
Musculo-skeletal (Conventional)		P	P	P	P	P	P			
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)	$\top$	$\top$	1-	1					114 #1(0225)	

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:	
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,	_
R+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,	_
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE	_
**small organs (breast, testes, thyroid, penis)	-

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

15L8w

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic	1_					ļ	P P		p*	
Fetal		P	P	P	P	P	P	<del></del>	P*	P
Abdominal	Τ	P	P	P	P	P	P	<del> </del>	P*	P
Intraoperative Abdominal		P	P	P	P	P				P
Intraoperative Neurological	1	P	P	P	P	P	P	<u> </u>	P*	
Pediatric	+-	P	P	P	P	P	P		P*	P
Small Organ (specify)**	1-	P	P	Р	P	P	Р		P*	P
Neonatal Cephalic	T-	T		l				<u> </u>	<del> </del>	
Adult Cephalic	7						ļ	ļ <u> </u>	p*	
Cardiac		P	P	P	P	P	P	_	- F	<del> </del>
Trans-esophageal	$\neg$		$I_{-}$					_	<del>-</del>	
Transrectal				<u> </u>						
Transvaginal	$T_{-}$		<u> </u>	<u> </u>					<del> </del>	<del></del>
Transurethral									<del> </del>	<del></del>
Intravascular	_ i	<u> </u>	<u> </u>	<u> </u>			<del> </del>	1		P
Peripheral Vessel		P	P	P	P	P	P			<del>-   -                                 </del>
Laparoscopic				ļ					p*	- P
Musculo-skeletal (Conventional)		P	P	P	P	P	P			
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)	$\neg$						V051120 #V04			

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:  *Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
*Combinations include: B+M, B+PWD, B+Color Doppler, B+Color Doppler, B+CWD+Color Doppler, B+C
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
**small organs (breast, testes, thyroid, penis)

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal

and Radiological Devices

510(k) Number \_

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510(k) Number (if known):

Device Name:

**V5M TEE** 

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						Ţ		<del> </del>		<del> </del>
Fetal	Τ.	<u> </u>		<u> </u>	<u> </u>	ļ	P -		p*	P
Abdominal		P	P	P	P	P	r	<del> </del>		<del> </del>
Intraoperative Abdominal					<u> </u>			<u> </u>		<del> </del>
Intraoperative Neurological				<u> </u>			1		p*	P
Pediatric		P	P	P	P	P	P	<del>_</del>	- r	<del> </del> -
Small Organ (specify)**	7				<u> </u>				<u> </u>	<u> </u>
Neonatal Cephalic	_			Ī	<u> </u>			<del> </del>		<del> </del>
Adult Cephalic					<b>_</b>		<del>                                     </del>	<del> </del>	P*	P
Cardiac	$\top$	P	P	P	P	P	P	<del> </del>	P*	P
Trans-esophageal	$\top$	P	P	P	P	P	P		<del>  - 1</del>	+
Transrectal					<u> </u>				<del> </del>	
Transvaginal			<u> </u>							
Transurethral			<u> </u>						<del> </del>	
Intravascular			1_							+
Peripheral Vessel				<del></del>						
Laparoscopic						<del></del>			<del>- </del>	
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)									-	_
Other (specify)		T T							1	

P=previously cleared by the FDA under premarket notifications #K052021, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:  *Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B. DWD: Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

V7M TEE

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						ļ	ļ	<del></del>	<u> </u>	<del> </del>
Fetal	1					<u> </u>	ļ <u>.</u>		p*	<del>  _ р</del>
Abdominal		P	P	P	P	P	P	<del> </del>		<del> </del> -
Intraoperative Abdominal						ļ	<u> </u>	ļ		<u> </u>
Intraoperative Neurological			ļ						p*	P
Pediatric	<b>T</b>	P	P	P	P	P	P		P*	+ - r
Small Organ (specify)**										
Neonatal Cephalic						<u></u>			<u> </u>	<del> </del>
Adult Cephalic	┪ ̄	1		l		<u> </u>			p*	P
Cardiac	1	P	P	P_	P	P	P			P
Trans-esophageal		P	P	P	P	P	P		P*	r
Transrectal						<u> </u>	ļ			
Transvaginal	Ţ					<u> </u>	<u> </u>			<del></del>
Transurethral				<u> </u>		<u> </u>	<del>-  </del>	<del>- </del>	<del> </del>	
Intravascular			$oldsymbol{oldsymbol{oldsymbol{oldsymbol{\bot}}}$							<del> </del>
Peripheral Vessel			_			ļ		<u> </u>		
Laparoscopic				1					<del></del>	
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)	ヿヿ	$\top$		7			W051120 #V0/		_]	

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, and #K022567.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number \_\_\_\_\_

510(k) Number (if known):

Device Name:

V7B TEE

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic							<del> </del>	<del></del> -	<del> </del>	<del> </del>
Fetal		<u> </u>			<u> </u>		P		p*	P
Abdominal		P	P	P	P	P	- r	<del> </del>		<del> </del>
Intraoperative Abdominal					<u> </u>			<u> </u>	<del> </del>	
Intraoperative Neurological									P*	P
Pediatric		P	P	P	P	P	P	<del></del>	<del></del>	<del>                                     </del>
Small Organ (specify)**										<del> </del>
Neonatal Cephalic				<u> </u>			<u> </u>			<del></del>
Adult Cephalic				<u> </u>			ļ n	<del>- </del>	p+	P
Cardiac		P	P	P	P	P	P		p*	P
Trans-esophageal		P	P	P	P	P	P	<del></del>		<del></del> -
Transrectal						<u> </u>		<del></del>	<del></del>	<del></del>
Transvaginal			╽_			<u> </u>			<del>-</del>	
Transurethral			<u> </u>	1				<del> </del>		
Intravascular			<u> </u>						<del></del>	
Peripheral Vessel			1_		<b>↓</b>					
Laparoscopic			1							
Musculo-skeletal (Conventional)				<u> </u>						
Musculo-skeletal (Superficial)									<u> </u>	
Other (checifu)	$\neg \vdash$	1					 #K051139, #K0		<u></u>	200667

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, and #K022567.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Padiological Devices

510(k) Number \_\_\_\_\_

510(k) Number (if known):

Device Name:

3V2c

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						P	P		p*	P
Fetal		P	P	P	Р		P		p*	P
Abdominal		P	P	P	P	P	<u> </u>	<del>                                     </del>	<del> </del> -	1
Intraoperative Abdominal					<u> </u>			-		
Intraoperative Neurological				ļ		<u> </u>			p*	P
Pediatric		P	P	P	P	P	Р	_	<del> '-</del>	<del> </del>
Small Organ (specify)**							<u> </u>			<u> </u>
Neonatal Cephalic			<u> </u>	<u> </u>		ļ	ļ	_	P*	P
Adult Cephalic		P	P	P	P	P	P		P*	P
Cardiac		P	P	P	P	P	P	<del> </del>	<u> </u>	<del> </del>
Trans-esophageal			1			<u> </u>		<del></del>		<del></del>
Transrectal			╽_	<u> </u>						
Transvaginal		1							<del> </del>	
Transurethral									<del>                                     </del>	
Intravascular		╽.								
Peripheral Vessel							<del> </del>			
Laparoscopic							<del> </del>	<del></del>		
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)									p*	
Other (specify)***		P	P	P	P	P	P #K051139, #K04			

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, and #K022567.

Additional Comments:  *Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+Clarify VE
***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

4V1

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic	士.						P		p*	P
Fetal		P	P	P	P	P	.1		p*	P
Abdominal		P	P	P	P	P	P	<del> </del>		P
Intraoperative Abdominal		P	P	Р	P	P	r —	ļ	<u> </u>	<u> </u>
Intraoperative Neurological								<u> </u>	D*	P
Pediatric		P	P	P	P	P	P		<u> </u>	- r
Small Organ (specify)**										ļ
Neonatal Cephalic	1		П		<u> </u>				<del> </del>	
Adult Cephalic	1	1		I			<u> </u>		p*	P
Cardiac	1	P	P	P	P	P	P		- r	<del>  -                                   </del>
Trans-esophageal	7		T							
Transrectal		]		<u> </u>	<u> </u>	_			_\	<del> </del>
Transvaginal										<del></del>
Transurethral		<u> </u>		1				<del> </del>	<del></del>	<del> </del>
Intravascular		1_								P
Peripheral Vessel		P	P	P	P	P	P		<del>                                     </del>	<del></del>
Laparoscopic			$\perp$				1		<del></del>	
Musculo-skeletal (Conventional)									<u> </u>	
Musculo-skeletal (Superficial)										<u> </u>
Other (specify)		1	1	7	_		W051130 #K04			

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, and #K022567.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B4PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices,

510(k) Number.

510(k) Number (if known):

Device Name:

4V1c

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic							P	<del> </del>	p*	P
Fetal		P	P	P	P	P	·	<del>                                     </del>	P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	Р	P	P	Р	<u>  </u>	p*	P
Intraoperative Neurological		P	P	P	P	P	P	l		
Pediatric	┪	P	P	P	P	P	P		P*	P
Small Organ (specify)**	<del>                                     </del>	1_						ļ		
Neonatal Cephalic		$\Box$		l	J			<del>-}</del>	P*	P P
Adult Cephalic	1	P	P	P	P	P	P		P*	P
Cardiac	7	P	P	P	P	P	P		<del>                                     </del>	<del> </del>
Trans-esophageal		T						<u> </u>	<del></del>	<del> </del>
Transrectal			<u> </u>			<u> </u>		<b></b>	<u> </u>	
Transvaginal		1_	<u> </u>	<u> </u>				<u> </u>	- <del> </del>	
Transurethral				<u> </u>				<del> </del>	<del> </del>	<del></del>
Intravascular		1_					<del> </del>	<del> </del>	p*	P
Peripheral Vessel		P	P	P	P	P	P			<del> </del>
Laparoscopic										<del> </del>
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										ļ
Other (specify)***	$\dashv$	P	P	P	P	P	P	_l	P*	P

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, and #K022567

Additional Comments:  *Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
R+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
***neonatal cardiac

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal

and Radiological Devices

510(k) Number (if known):

Device Name:

4V2

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic							P	-	P*	P
Fetal	<u></u>	P	P	P	P	P	P		p*	P
Abdominal		P	P	P	P	P	PP		<del>                                   </del>	<del> </del> -
Intraoperative Abdominal			_	<u> </u>				ļ	<u> </u>	<u> </u>
Intraoperative Neurological								<u> </u>	p*	P
Pediatric		P	P	P	P	P	P	<del> </del>	<del>                                     </del>	+
Small Organ (specify)**					ļ					ļ
Neonatal Cephalic						<u> </u>			<del></del>	
Adult Cephalic						<u> </u>		<b></b>	1	<del></del>
Cardiac									<del></del>	<del>-                                    </del>
Trans-esophageal						_ <del> </del>	ļ	<u> </u>		
Transrectal			<u> </u>			1	<del></del>		<del></del>	
Transvaginal			<u> </u>			<del></del>		<del></del>	- <del> </del>	
Transurethral		1	1_						<del></del>	
Intravascular							<del> </del>		<del>- </del>	
Peripheral Vessel			4—			_	<del></del>	<del></del>	+	
Laparoscopic		┶	_					<del> </del>	<del> </del>	
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)	$\dashv$	$\top$					W051130 #K04			

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+PWD+Color Doppler, B+CWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

5V2c

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic								<u> </u>	p*	P
Fetal		P	P	P	P	P	Р		p+	P
Abdominal		P	P	P	P	P	P	<del></del>		<del> </del> -
Intraoperative Abdominal							<u> </u>		<u> </u>	
Intraoperative Neurological									P*	P -
Pediatric		P	P	P	P	P	P		<del>                                     </del>	+
Small Organ (specify)**										
Neonatal Cephalic				]	<u> </u>	<u> </u>			<u> </u>	<del>- </del>
Adult Cephalic						<u> </u>	<del>                                     </del>	<u> </u>	P*	P
Cardiac		P	P	P	P	P	P			+
Trans-esophageal										<del></del>
Transrectal				<u> </u>	ļ	<del>- </del>				<del> </del>
Transvaginal			1							<del> </del>
Transurethral		_	ᆚ	<u> </u>						
Intravascular		$\perp$		<u> </u>			P	<del></del>	P*	P
Peripheral Vessel		P	P	P	P	P			<del></del>	
Laparoscopic			1	<u> </u>		<del> </del>		<del></del>		
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										P
Other (specify)***	$\neg$	F	P	P	P	P	P #V051130 #K04		P*	

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

dditional Comments:
Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
+H+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
+MI+Power Doppics, D+1 WD+1 owar Doppies, D+0+2-1
**neonatal cardiac

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

7V3c

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						P	P P	<del> </del>	P*	P
Fetal	<u> </u>	P	P	P	P	P	P	<del> </del>	P*	P
Abdominal	J	P	P	P	P		- P	<del></del>	P*	P
Intraoperative Abdominal		P	P	P	P	P	P	<del> </del>	p*	P
Intraoperative Neurological		P	P	P	P	P				P
Pediatric	+-	P	P	P	P	P	P		P*	r
Small Organ (specify)**									P*	P
Neonatal Cephalic		P	P	P	P	P	P		P*	
Adult Cephalic		丁					ļ <u> </u>		P*	P
Cardiac	T-	P	P	P	P	P	P			<del></del>
Trans-esophageal		7_		I				<u> </u>	<del>-</del>	<del></del>
Transrectal			L.,					<del>-  </del>		
Transvaginal		١.	١							
Transurethral			<u> </u>					<del></del>		+
Intravascular		1_					<del> </del>	+	p*	P
Peripheral Vessel		P	P	P	P	P	Р	<del>-</del>	<del>                                     </del>	<del> </del>
Laparoscopic		Ш.						<del>-                                    </del>	<del> </del>	
Musculo-skeletal (Conventional)									-	
Musculo-skeletal (Superficial)									p*	P
Other (specify)***		P	P	P	P	P	P #K051130 #K04	<u>1</u>		

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:  Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+Clarify VE B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
**neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number \_\_\_\_

510(k) Number (if known):

Device Name:

8V3

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						P	P	<u> </u>	p*	P
Fetal		P	P	P	P	.1	P	+	p+	P
Abdominal		P	P	P	P	P	P	<del>-</del>	P*	P
Intraoperative Abdominal		P	P	P	P	P	<u> </u>		p*	P
Intraoperative Neurological		P	P	P	P	P	P			P -
Pediatric	+-	P	P	P	P	P	P		P*	<u> </u>
Small Organ (specify)**										P
Neonatal Cephalic	1	P	P	P	P	PP	P		P*	- r
Adult Cephalic								<u> </u>	p*	P -
Cardiac		P	P	P	P	P	Р	<u> </u>	P*	<u>_</u>
Trans-esophageal	1	T-						<u> </u>		<del> </del>
Transrectal							<del></del>	<b>_</b>		
Transvaginal			1				<u> </u>	<del> </del>		
Transurethral			1_		·	<del> </del>		<del> </del>	<del></del>	<del> </del>
Intravascular			1_				<del> </del>		P*	P
Peripheral Vessel		P	P	P	P	P	<u>P</u>	_	<del>                                     </del>	<del>-                                    </del>
Laparoscopic									<del></del>	
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***	$\dashv$	P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, and #K032114.

Additional Comments:  *Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+Clarify VE  B+M+Power Doppler, B+PWD+Power Doppler, B+Clarify VE
***neonatal cardiac

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

8V5

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic	1_						P		P*	Р —
Fetal	1	P	P	P	P	P	1	-	P*	P
Abdominal		P	P	P	P	P	P	<del>-  </del>	P*	P
Intraoperative Abdominal		P	P	P	P	P	P			
Intraoperative Neurological		P	P	P	P	P	P	ļ	P*	
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic	1	P	P	P	P	P	P		P*	P
Adult Cephalic					<u> </u>				p*	P
Cardiac	1	P	P	P	P	P	P		P*	<del></del>
Trans-esophageal				I		<u></u>				<del></del>
Transrectal				<u> </u>					<del></del>	
Transvaginal				<u> </u>			<del></del>			
Transurethral							<del></del>		<del>- </del>	<del>- </del>
Intravascular			1	<b>⅃</b>			<u> </u>		P*	P
Peripheral Vessel		P	P	P	P	P	P			<del></del>
Laparoscopic			1						<del> </del>	<del> </del>
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***	$\top$	P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:	
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,	
B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,	
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE	
***neonatal cardiac	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

10V4

Intended Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						P	P		P*	P
Fetal		P	P	P	P	1	P	<del> </del>	p*	P
Abdominal		P	P	P	P	P	P	+	p*	P
Intraoperative Abdominal		P	P	P	P	P			P*	P
Intraoperative Neurological		P	P	P	P	P	P			
Pediatric	<del>                                     </del>	l P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	Р	P	P	Р	<u> </u>	p*	P
Neonatal Cephalic	$\dashv$	P	P	P	P	P	P		P*	P
Adult Cephalic	$\neg$		1					_	p*	P
Cardiac	7	P	P	P	P	P	P		<u> </u>	<del> </del>
Trans-esophageal				Ī			<u> </u>			
Transrectal							<u> </u>		- <del> </del>	
Transvaginal		"	<u> </u>	<u> </u>			<del></del>		<del>-</del>	+
Transurethral			<u> </u>	<u> </u>			_	<del></del>	<del></del>	
Intravascular			j	<u> </u>					<del> </del>	_
Peripheral Vessel						<u> </u>				<del></del>
Laparoscopic		1		<u> </u>		<u> </u>				
Musculo-skeletal (Conventional)										<u> </u>
Musculo-skeletal (Superficial)										P
Other (specify)***		P	P	P	P	P	P		P*	

P=previously cleared by the FDA under premarket notifications #K051139, #K041319, #K032114, and #K022567.

Additional Comments:  *Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
R+PWD+Color Doppler B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarity VE
**small organs (breast, testes, thyroid, penis)
***neonatal cardiac

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Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal,

and Radiological Devices

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Color Velocity Imaging		Harmoni Imaging
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041319, #K03	32114, #K022	567,
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510(k)	Number	(if	known)	):
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Device Name:

Sequoia Ultrasound System

Transducer:

AcuNav (IC10V5 or 10F) Ultrasound Catheter

Indications for Use:

The AcuNav™ Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel

anatomy and physiology as well as visualization of other devices

in the heart.

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic						ļ	<u>                                     </u>	<u> </u>	ļ <u>.</u>	<del></del>
Fetal	Ϊ	<u>l</u> _				<u> </u>	ļ	<u>- </u>	<del> </del>	<del> </del>
Abdominal						<del> </del>	<u> </u>	<del></del>		+
Intraoperative Abdominal							<u> </u>	<u> </u>		<del> </del>
Intraoperative Neurological			   		<u> </u>					
Pediatric					<u> </u>				<del>-</del>	
Small Organ (specify)**									<u> </u>	
Neonatal Cephalic	1	Τ_							ļ	
Adult Cephalic		Ι	<u> </u>			<u> </u>			P*	P
Cardiac		P	P	P	P	P	P		ļ <u>-</u>	<del>  -                                   </del>
Trans-esophageal			<u>L</u>	<u> </u>					<del>- </del>	
Transrectal			<u> </u>					<del>-  </del>	4	
Transvaginal		<u> </u>	<u> </u>	<u> </u>						<del></del>
Transurethral		1_	<u>L.</u>		<u> </u>				p*	P
Intra-luminal		P	P	P	Р	P	P		1	
Peripheral Vessel			<u> </u>					<del>  -</del>	<del>-  </del>	<del></del>
Laparoscopic			1_	<u> </u>	_		<b>_</b>			+
Musculo-skeletal (Conventional)									<u> </u>	
Musculo-skeletal (Superficial)									<u> </u>	P
Other (Intra-Cardiac)		P	P	P	P	P	P		P*	

P=previously cleared by the FDA under premarket notifications #K051139, #K033650, #K033196, and #K992631.

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109
(Division Sign-Off) Division of Reproductive, Abdominal,
and Radiological Devices 252410

510(k) Numb	oer (if	known)
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Device Name:

Sequoia Ultrasound System

Transducer:

**AcuNav 8F Ultrasound Catheter** 

Indications for Use:

The AcuNav™ Ultrasound Catheter is intended for intra-cardiac

and intra-luminal visualization of cardiac and great vessel

anatomy and physiology as well as visualization of other devices

in the heart.

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										<del></del>
Fetal		1				1	<u> </u>	<del> </del>	<del> </del>	<del> </del>
Abdominal	]				<u> </u>	1		<del> </del>		1
Intraoperative Abdominal	T				<u> </u>			<b>-</b>		<u> </u>
Intraoperative Neurological					<u> </u>					<u> </u>
Pediatric					<del></del>		<u> </u>	<del> </del>	<del> </del>	<del> </del>
Small Organ (specify)**										<b></b>
Neonatal Cephalic						<u> </u>	<u> </u>	<u> </u>		<del> </del>
Adult Cephalic			<u> </u>			1	J		P*	P
Cardiac		P	P	P	P	P	P	<del> </del>	P*	<u> </u>
Trans-esophageal							<u> </u>			
Transrectal	]			<u> </u>					<del> </del>	
Transvaginal			<u> </u>				_ <b> </b>			<del></del>
Transurethral								<del></del>	p*	P
Intra-luminal	<u> </u>	P	P	P	P	P	Р			<del></del>
Peripheral Vessel								<del></del>		<del></del>
Laparoscopic			1					<b></b>	<del></del>	-
Musculo-skeletal (Conventional)										<u> </u>
Musculo-skeletal (Superficial)									<u> </u>	
Other (Intra-Cardiac)		P	P	P	P	P	P		P*	<u> P</u>

P=previously cleared by the FDA under premarket notifications #K051139, and #K042593.

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices KU5 24

510(k) Number (if known):

Device Name:

Apollo

Indications for Use:

Ultrasound imaging or fluid flow analysis of the human

body as follows:

Clinical Application	A	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic						P	P			P	┼──	P
Fetal	_	P	P	Р	P	P	P	<del> </del>	P*	P		P
Abdominal		P	P	P	P		P	<del> </del>	P*	P		P
Intraoperative Abdominal		P	P	P	P	P			_		<del> </del>	┼
Intraoperative Neurological								<u> </u>	P*	P	<del> </del>	P
Pediatric	1	P	P	P	P	P	P	<del> </del>	<del> </del>	<del></del>	<del> </del>	<del>  -</del>
Small Organ (specify)**											<u> </u>	<del> </del>
Neonatal Cephalic							<u> </u>			<u> </u>	-	-
Adult Cephalic	1_		1_	<u> </u>			<u> </u>	<del> </del>	P*	Р -	<del>                                     </del>	P
Cardiac		P	P	P	Р	P	ļ	<del> </del>	<del></del>	<del> </del>	_	<del> </del>
Trans-esophageal	L		<u> </u>	<u> </u>	<u> </u>			<del> </del>	<del></del>	<del></del>	<del></del>	1
Transrectal	<u> </u>	$\perp$	1_	<u> </u>		_}						<del> </del>
Transvaginal		1_					<del> </del>			<del></del>		<del>   </del>
Transurethral	1_			<u> </u>				<del>-</del>		<del></del>		
Intravascular		1_	$\perp$			<del></del>	P		- p*			P
Peripheral Vessel		P	P	P	P	P	P	+	<del></del>	<del></del>		<del> </del>
Laparoscopic	$\perp$				<b>↓</b>		<del> </del>			<del>-</del>	+-	+-
Musculo-skeletal (Conventional)									<u> </u>			
Musculo-skeletal (Superficial)												- P
Other (specify)***		F			P	P			P*	P		

P=previously cleared by the FDA under premarket notification #K051139.

Additional Comments:
Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler,
R+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,
B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
**small organs (breast, testes, thyroid, penis)
***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109
David Ou Segram
(Division Sign-Off)
Division of Reproductive, Abdominal,
au Padiological Devices 05240
510(k) Number